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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,845	12/20/2006	Richard L. Friedman	293875US96PCT	1053
22850 7590 07/12/2010 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER DEVI, SARVAMANGALA 7N				
ART UNIT 1645		PAPER NUMBER		
NOTIFICATION DATE 07/12/2010		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com

oblonpat@oblon.com

jgardner@oblon.com

# Office Action Summary

**Application No.**

10/588,845

**Applicant(s)**

FRIEDMAN ET AL.

**Examiner**

S. Devi, Ph.D.

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03/24/10.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 53-71 is/are pending in the application.
- 4a) Of the above claim(s) 56-58, 60-65, 67-69 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-55, 59, 66 and 70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendment**

- 1) Acknowledgment is made of Applicants' amendment filed 03/24/10 in response to the non-final Office Action mailed 11/24/09.

### **Status of Claims**

- 2) Claims 1-52 have been canceled via the amendment filed 03/24/10.  
New claims 53-71 have been added via the amendment filed 03/24/10.  
Claims 53-71 are pending.  
Claims 56-58, 60-65, 67-69 and 71 are currently withdrawn from consideration as being directed to non-elected invention and/or non-elected species. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03.  
Claims 53-55, 59, 66 and 70 are under examination.

### **Prior Citation of Title 35 Sections**

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Maintained**

- 5) The objection to the specification made in paragraphs 7(a), 7(b) and 7(c) of the Office Action mailed 11/24/09 is maintained for the reasons set forth therein.

### **Objection(s) Moot**

- 6) The objection to claims 2-5 and 49 made in paragraph 12 of the Office Action mailed 11/24/09 is moot in light of Applicants' cancellation of the claims.

### **Objection(s) to Specification**

- 7) The instant specification is objected to for the following reason:

37 CFR 1.75(d)(1) provides, in part, that 'the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.'

New claims 53 and 55 include the new limitations: 'a length of at least 5 nm' and 'a length of at least 10 nm' respectively, which lack clear antecedent basis in the as-filed specification.

### **Rejection(s) Moot**

8) The rejection of claims 2-5 made in paragraph 9 of the Office Action mailed 11/24/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

9) The rejection of claims 1-5, 45 and 49 made in paragraph 11 of the Office Action mailed 11/24/09 35 U.S.C. § 102(b) as being anticipated by Reed *et al.* (WO 97/09429 A2 – Applicants' IDS), is moot in light of Applicants' cancellation of the claims. Applicants' arguments have been considered, but are moot in view of the cancellation of the claims and the new rejection set forth below.

### **New Rejection(s) Necessitated by Applicants' Amendment**

#### **Rejection(s) under 35 U.S.C. § 112, First Paragraph**

10) The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### **Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)**

11) Claims 53 and 55 and those dependent therefrom are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claims 53 and 55 include the new limitations: 'a length of at least 5 nm' and 'a length of at least 10 nm' respectively. The original claim 3 recited a length of at least about 5 to about 10 'microns'. The paragraph bridging pages 6 and 7 of the specification also describes the length of

the fibers as being generally at least about 5 to about 10 'microns'. Applicants do not point to parts of the specification that provide descriptive support for the above-identified limitation. Therefore, the above-identified limitation in the new claims is considered to be new matter. MPEP 608.04(c).

Applicants are invited to point to specific line and page numbers of the specification, as originally filed, that provide descriptive support for the limitations identified above, or remove the new matter from the claim. Applicants should specifically point out the support for any amendment made to the disclosure. See MPEP 714.02 and 2163.06.

### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

- 12)** The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

- 13)** Claims 53-55 and 59 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claim 53 is indefinite in the limitations: 'about 2 to 7', because it is unclear what range is encompassed in this limitation. The limitation 'about' is a relative term which is not specifically defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the claim. For example, is a range of  $2 \pm 10$  or  $7 \pm 20$  encompassed within the scope of the limitation 'about 2 to 7'?

(b) Claims 54, 55 and 59, which depend from claim 53, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

### **Rejection(s) under 35 U.S.C. § 102**

- 14)** The following is a quotation of the appropriate paragraph(s) of 35 U.S.C. § 102 that form the basis for the rejection(s) under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**15)** Claims 53-55, 59, 66 and 70 are rejected under 35 U.S.C. § 102(b) as being anticipated by Reed *et al.* (WO 97/09429 A2, of record).

Reed *et al.* taught isolated and purified (i.e., substantially free of cells) *Mycobacterium tuberculosis* polypeptide antigens (i.e., pilin protein) of a molecular weight of 14 Kd. One such antigen comprises the instantly recited amino acid sequence of SEQ ID NO 5, i.e., the amino acid sequence having the accession number AAW32374. The antigens are produced by a method wherein *M. tuberculosis* cells are subjected to sonication (i.e., mechanical shearing) and isolating the antigens following centrifugation. See Examples 2-3; pages 9, 14, 30 and 134; and SEQ ID NO: 87, the amino acid sequence of YYWCPG. The prior art polypeptide antigen has the amino acid sequence that is 100% identical in structure with the instantly recited SEQ ID NO: 5. See the sequence alignment depicted below.

AAW32374  
ID AAW32374 standard; protein; 103 AA.  
AC AAW32374  
DT 15-JUN-2007 (revised)  
DT 13-JAN-1998 (first entry)  
DE Mycobacterium tuberculosis antigen YYWCPG.  
KW Antigen; immunogen; vaccine; tuberculosis; non specific adjuvant;  
KW skin testing; M.tuberculosis; BOND\_PC; SECRETED PROTEIN ANTIGEN;  
KW SECRETED PROTEIN ANTIGEN [Mycobacterium tuberculosis H37Rv];  
KW SECRETED PROTEIN ANTIGEN [Mycobacterium bovis AF2122/97];  
KW Secreted protein antigen [Mycobacterium bovis BCG str. Pasteur 1173P2]  
KW secreted protein antigen [Mycobacterium tuberculosis H37Ra];  
KW secreted protein antigen [Mycobacterium tuberculosis C];  
KW secreted protein antigen [Mycobacterium tuberculosis str. Haarlem].  
OS Mycobacterium tuberculosis.  
PN WO9709429-A2.  
PD 13-MAR-1997.  
PF 30-AUG-1996; 96WO-US014675.  
PR 01-SEP-1995; 95US-00523435.  
PR 22-SEP-1995; 95US-00532136.  
PR 22-MAR-1996; 96US-00620280.  
PR 05-JUN-1996; 96US-00658800.  
PR 12-JUL-1996; 96US-00680573.  
FA (CORI-) CORIXA CORP.  
PI Reed SG, Skeiky YAW, Dillon DC, Campos-Neto A, Houghton R;  
PI Vedvick TH, Twardzik DR;  
DR WPI; 1997-192904/17.  
DR N-PSDB; AAT91421.  
DR PC:NCBI; gi31620089.  
PT New immunogenic polypeptide(s) from soluble M. tuberculosis antigens -  
PT useful for diagnosis of M. tuberculosis infection.  
PS Example 3; Page 134; 190pp; English.

CC A new immunogenic polypeptide has been developed comprising an immunogenic part of a soluble Mycobacterium tuberculosis antigen (or its variant differing only in conservative substitutions and/or modifications). The present sequence represents a M.tuberculosis antigen, YWCPG. The immunogenic polypeptide can be used to diagnose M.tuberculosis infection by forming complexes with specific antibodies in the sample. Fragments of DNA encoding the immunogenic polypeptide can be used as diagnostic primers or probes and agents that bind to the antigen, especially monoclonal antibodies or equivalent polyclonal antibodies, are also used for diagnosis  
SQ Sequence 103 AA;

Query Match 100.0%; Score 598; DB 1; Length 103;  
Best Local Similarity 100.0%; Pred. No. 8.7e-54;  
Matches 103; Conservative 0; Mismatches 0; Indels 0; Gaps 0.

```
Qy      1 MYRFACRTLMLAACILATGVAGLVGAQSAQAQTAPVPDYYWCPGQFFDPAWGNWDPYTC 60
          |||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1 MYRFACRTLMLAACILATGVAGLVGAQSAQAQTAPVPDYYWCPGQFFDPAWGNWDPYTC 60

Qy      61 HDDFHRSDSGPDHSRDYPGPILGPFVLDPGAAPPPPAAGGGA 103
          |||||||||||||||||||||||||||||||||||||||
Db      61 HDDFHRSDSGPDHSRDYPGPILGPFVLDPGAAPPPPAAGGGA 103
```

Since the prior art product and the instantly claimed product have the same monomeric structure and the same *M. tuberculosis* origin and are both produced by separation via mechanical shearing, the prior art product is expected to have the same characteristics or properties recited in claims 53, 55 and 66. Furthermore, due to the long length of the sequence, the prior art product would be expected to be necessarily immunogenic. 'Products of identical chemical composition can not have mutually exclusive properties.' A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicants recite are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 53-55, 59, 66 and 70 are anticipated by Reed *et al*.

## Remarks

- 16) Claims 53-55, 59, 66 and 70 stand rejected.
- 17) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**18)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted to the Office's Central Rightfax number 571-273-8300 via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week.

**19)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

**20)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/  
Primary Examiner  
AU 1645

July, 2010